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## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response and Supplemental Response after Final Office Action filed 12/14/09 and 12/23/09 is acknowledged. The Responses have been entered.

Claims 75-86, 89, 91 and 92 are pending in this action. Claims 75 and 85 have been amended via Applicant amendment. Claim 85 has also been amended via Examiner's Amendment. Claims 1-74, 87, 88 and 90 have previously been cancelled. Claims 75-86, 89, 91 and 92 are allowed.

### **EXAMINER'S AMENDMENT**

The application has been amended as follows:

#### In the Claims:

In claim 85, the term "physiologic" has been changed to **--physiological--**.

(This amendment has been made to recite proper antecedent basis).

### ***Allowable Subject Matter***

Claims 75-86, 89, 91 and 92 are allowed.

The following is an examiner's statement of reasons for allowance: The primary reasons for allowance are that the prior art does not disclose nor teach the instantly claimed dosage form having a hydrophobic means for sequestering the opioid antagonist of the instant invention. The prior art further fails to disclose or teach an intact dosage form that releases less than 15% by

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weight of the opioid antagonist within 36 hours based on the in-vitro dissolution in a dissolution bath. The prior art also fails to teach that the amount of opioid antagonist released from the dosage form which has been administered intact is less than an amount bioequivalent to 0.125 mg of naltrexone. In addition, the prior art also fails to teach that the amount of opioid antagonist released from the dosage form which has been tampered with is in an amount bioequivalent to 0.25 mg of naltrexone.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

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January 11, 2010